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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,438	12/31/2001	David L. Hurley		8701

36931 7590 09/22/2004

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EXAMINER

KELLY, ROBERT M

ART UNIT : PAPER NUMBER

1632

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/032,438

Applicant(s)

HURLEY, DAVID L.

Examiner

Robert M Kelly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, drawn to nucleic acid sequences encoding Zn-16, and a host cell comprising such sequences, classified in class 536, subclass 23.1.
- II. Claims 7 and 19, drawn to a method of detecting a nucleic acid, classified in class 435, subclass 6.
- III. Claim 8, drawn to a method of controlling the expression of a gene, classified in class 514, subclass 44.
- IV. Claims 9, 10, and 17-18, drawn to a polypeptide and a method of controlling the expression of gene products at a multiplicity of loci in the genome of an organism, classified in class 435, subclass 183.
- V. Claim 11, drawn to a method of identifying an agent that changes the level of expression of a growth hormone gene, classified in class 435, subclass 6.
- VI. Claim 12 and 13-16, drawn to a method of controlling the rate of growth of an organism, classified in class 514, subclass 44.
- VII. Claim 20, drawn to a method of treating a human patient, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Groups II-VII represent patentably distinct inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

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operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different steps that require different, non-coextensive, structural and functional considerations. To wit, Group II requires measuring the extent of hybridization between two different nucleic acids; Group III requires binding a transcriptional regulatory molecule to a nucleic acid; Group IV requires a polypeptide and altering such polypeptide before using it on the genes of a genome; Group V requires combining agents with nucleic acids and observing changes in transcription; Group VI requires introducing a nucleic acid construct linked to a heterologous flanking sequence into an organism to alter the expression of endogenous growth hormone genes; and Group VII requires the administration of a nucleic acid into a human. Each of these method steps requires different structural and functional considerations, and such considerations are non-coextensive.

The inventions of Group I is related to Groups II-III and V-VII as product is related to process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group I may be used in the methods of Groups II-III and VI-VIII. Moreover, such nucleic acids have other uses: i.e., making protein. Lastly, because of these multiple uses, as well as unclaimed uses, which are caused by different structures and functions, these nucleic acids would require different, non-coextensive, search and examination considerations.

The invention of Group I is patentably distinct from the invention of Group IV.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together, and the nucleic acids have different structure from the peptides, and, due to that structure, they also have different structural considerations. Moreover, although the nucleic acids may be used to make the peptides, they are also have other distinct uses (See previous paragraphs). Therefore, because they have distinct structural and functional considerations, which are non-coextensive, the search and examination of these inventions are different and non-coextensive.

Because these inventions are distinct for the reasons given above and the search and examination required for any Group is different from that required of any other group restriction for examination purposes as indicated is proper. Also, although one may argue that certain groups are similarly classified, these groups represent broad categories, e.g., all gene therapy and all analytical methods, such that the search for one group would not be coextensive with that of any other group within that category.


Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M Kelly whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER